

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA, ex. rel.	)	
JUAN N. WALTERSPIEL, M.D., F.A.A.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:12CV773
	)	
BAYER A.G., QUINTILES TRANSNATIONAL	)	
CORP., JOHN DOE, JOE DOE, JANE DOE,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND RECOMMENDATION OF  
UNITED STATES MAGISTRATE JUDGE

This is a False Claims Act action under 31 U.S.C. § 3729(a) filed by *qui tam* Plaintiff/Relator Dr. Juan N. Walterspiel (“Plaintiff” or “Walterspiel”) against Bayer A.G. (“Defendant Bayer”) and Quintiles Transnational Corporation (“Defendant Quintiles”).<sup>1</sup> The United States has filed a Notice of Election to Decline Intervention [Doc. #29] in the action. The action is now before the Court on Defendant Quintiles’ Motion to Dismiss [Doc. #72] pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, the Court recommends that Defendant Quintiles’ Motion to Dismiss be granted. The Court also

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<sup>1</sup> Under § 3730(b) of the False Claims Act, a private person may bring an action in the name of the Government against a defendant who has knowingly presented or caused to be presented a false or fraudulent claim to the Government for payment. If the defendant is proven to have presented a false claim, the defendant is liable to the Government, and the private party who initiated the action may receive a percentage of the proceeds of the action or settlement, and reasonable expenses, costs, and attorney’s fees. See 31 U.S.C. § 3730(d); see also Cook Cnty., Ill. v. United States ex rel. Chandler, 538 U.S. 119, 122-23 (2003) (describing *qui tam* provisions of False Claims Act).

recommends that the claims against Defendant Bayer and the Doe Defendants be dismissed for failure to timely effectuate service of process, and that this action be dismissed.<sup>2</sup>

## I. FACTS, CLAIMS, AND PROCEDURAL HISTORY

### A. Facts and Procedural History

Plaintiff Walterspiel alleges that he is a licensed physician with experience in developing clinical trials for various drugs. According to the Complaint, in 2002, he worked as an independent contractor for Defendant Bayer, a German pharmaceutical company, to retrieve information from electronic study databases and present that information in narratives sent to Bayer's Independent Pediatric Safety Committee. Walterspiel alleges that Defendant Quintiles provides clinical trials, including medical study data collection and source verification services, to pharmaceutical companies such as Bayer. Defendant Quintiles collected Ciprofloxacin ("Cipro") pediatric data under contract with Defendant Bayer for two studies at issue in this action. In his Complaint, Walterspiel alleges that some of the database information provided by Defendant Quintiles and relied upon by Bayer was false. Defendant Bayer then allegedly used this data in studies provided to the Food and Drug Administration ("FDA"), which allowed Bayer to receive a six-month market exclusivity extension from the FDA for Cipro in December 2003. The six-month market exclusivity extension granted to Defendant Bayer ran from December 2003 until June 2004.

Walterspiel alleges that Jane Doe worked for Defendant Quintiles when it was collecting data on Cipro, reviewed the allegedly false data submitted to Defendant Bayer by Defendant

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<sup>2</sup> Defendant Bayer and the Doe Defendants have not appeared in the action.

Quintiles, and allowed the data to be submitted to Defendant Bayer while failing to disclose the falsity of the data. Walterspiel further alleges that Joe Doe worked for Defendant Bayer, reviewed the allegedly false data submitted to Defendant Bayer by Defendant Quintiles, and allowed the data to be submitted to the United States in support of Bayer's Cipro market exclusivity extension while failing to disclose the falsity of the data. Walterspiel alleges that John Doe worked for Defendant Quintiles, reviewed the Cipro pediatric study data submitted to Defendant Bayer, and observed irregularities in the data but failed to report this finding to his superiors or Defendant Bayer.

Walterspiel further alleges that Cipro is one of the most successful quinolone antimicrobials ever marketed. However, he further contends that it is known to destroy joint cartilage in juvenile animals, and that because of this, Cipro was considered contraindicated in children and not studied for market approval. Walterspiel contends that in August 2000, the Food and Drug Administration ("FDA") gave emergency use permission for Cipro in children for prophylaxis and treatment of pediatric inhalation anthrax based on bioterrorism concerns. Walterspiel further contends that this approval was conditional on further acquisition of reliable cartilage safety data from studies such as the two studies performed by Defendant Bayer that are at issue in this action.

In setting out his claims under the False Claims Act, Walterspiel contends that the fraud at issue in this action is the use of allegedly false data in the two Bayer studies, Nos. 100169 and 100201, that allowed Defendant Bayer to obtain the six-month Cipro market exclusivity extension. Walterspiel claims that he worked as a consultant to Bayer's Health Care Division

in Connecticut from about mid-2002 into early 2003. His responsibility was to retrieve information from electronic study databases and prepare written narratives whenever the data indicated a musculoskeletal or neurological adverse event. The narratives were then presented by Walterspiel to an independent adjudication committee, Bayer's Independent Pediatric Safety Committee, which then came to treatment-blinded assessments on causality.

Walterspiel claims that he found "improbable" joint angle measurements<sup>3</sup> in "some of the subjects under review" and asked Mrs. Perroncel, the senior clinical research associate that Bayer had assigned to him, to help him find the correct data. (Compl. ¶ 56.) Mrs. Perroncel allegedly agreed that the measurement data in question were "wrong," and brought the issue to the attention of Bayer's management. A neurologist leading the Cipro patent market exclusivity team purportedly asked Mrs. Perroncel to "confirm" the values in question by asking the investigators to sign letters confirming that these values were measured at their sites in the respective subjects and were correct. Mrs. Perroncel told Walterspiel shortly thereafter that signed letters from the investigators had arrived and were put into the file.

Walterspiel also alleges that he "noticed a lack of variability from measurement to measurement from some sites compared to others and noticed a lack of an analysis to flag any suspect data in advance of the committee's periodic reviews." (Id. ¶ 59.) Walterspiel says that in reviewing the data he "noted long rows of joint angle degree numbers that were obviously just 'filled in.' These numbers repeated themselves in endless fashion compared to those that were

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<sup>3</sup> According to Walterspiel, the maximal and minimal joint angle measurements were collected to detect short and long term joint cartilage or tendon damage that would lead to a restriction in the range of free joint movement.

within norm for age range and, with expected small variations from measurement to measurement, that other investigators recorded.” (Id. ¶ 64.) Walterspiel alleges that some of the data included values for joint angles that were scientifically impossible because the human limbs in question were not capable of such movement. Walterspiel concluded that “some of the data in the Bayer Cipro pediatric studies had been falsified.” (Id. ¶ 66.)

Walterspiel claims that the “false data and statements submitted by Defendants to the FDA which hid adverse effects of Ciprofloxacin in children were material to the FDA’s decision to approve the six month patent market exclusivity extension for Bayer for Cipro.” (Id. ¶ 60.) He further asserts that the FDA follows a standard under which once an investigator and/or assignee has been observed to have invented data, all data from the site are compromised and need to be discarded. Walterspiel alleges that based upon this practice, if the alleged fraud had been reported, Defendant Bayer could have been disqualified from future federal contracts for a period of years. According to Walterspiel, the fraudulent data should have been noticeable to Defendant Bayer physicians and to source verification personnel of Defendant Quintiles. Walterspiel contends that Defendant Quintiles and Defendant Bayer nevertheless “elected to take the option of knowingly submitting the Bayer Cipro pediatric study data to the FDA without disclosure of the false and fraudulent data, so as to not jeopardize Bayer’s \$0.5+ billion in Cipro sales and Quintiles Transnational’s current and future contracts with Bayer and other drug companies.” (Id. ¶ 73.)

With respect to the amount of the purported claim, Walterspiel alleges that prior to approval of the market exclusivity extension in December 2003, sales of Cipro worldwide were

over \$1.1 billion per year. He “estimates” that, during the six-month exclusivity extension period, Defendant Bayer enjoyed \$550 million in worldwide sales. He further estimates that 30% of this Bayer Cipro income is from the United States, or approximately \$165 million. He then estimates that the United States government’s share of U.S. sales—including Veterans Administration, Medicare, Medicaid, and DOD strategic national stockpile push pack rotation—is approximately 10%, or \$16.5 million. Walterspiel further estimates that the loss to the U.S. government from Defendant Bayer’s false claims relating to Cipro during the six-month market exclusivity extension is, at minimum, \$14.85 million, which Walterspiel contends is the difference between the amount paid (by his estimates), and the amount that would have been paid if a generic alternative were available.

#### B. Claims

Walterspiel includes five counts in his Complaint. In his Response to Defendant Quintiles’ Motion to Dismiss, he clarifies that only Counts 1-3 are alleged against Defendant Quintiles. (Pl.’s Resp. [Doc. #77] at 12 (“Counts 4 and 5 were intended to assert claims against Defendant Bayer, but not against Defendant Quintiles.”).)

Counts 1 through 3 allege violations of 31 U.S.C. § 3729(a). The relevant provisions of § 3729(a) generally prohibit the presentment of fraudulent claims for money or property “resulting in ‘a call upon the government fisc,’” U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 454 (4th Cir. 2013) (quoting Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999)), or the use of false records or statements material to such a

fraudulent claim, or a conspiracy to commit such a violation.<sup>4</sup> In the present case, Counts 1 and 2 relate to Walterspiel's assertions that Defendant Bayer, using allegedly fraudulent data provided by Defendant Quintiles, obtained the Cipro market exclusivity extension from the FDA, which allowed Defendant Bayer to charge falsely inflated prices for Cipro, which, in turn, caused the United States to pay more than it would otherwise have paid for Cipro from December 2003 to June 2004. In Count 3, Walterspiel alleges that Defendant Quintiles and Bayer conspired to perform the acts described in Counts 1 and 2 with the intent to defraud the United States.<sup>5</sup>

## II. DISCUSSION

### A. Motion to Dismiss

A plaintiff fails to state a claim on which relief may be granted under Federal Rule of Civil Procedure 12(b)(6) when the complaint does not “contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S.

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<sup>4</sup> Section 3729(a) was amended in 2009. Although the 2009 amendments are generally not retroactive, the changes to what was formerly Section 3729(a)(2) apply to “all claims under the False Claims Act . . . pending on or after [June 7, 2008.]” Pub. L. No. 111-21, § 4(f), 123 Stat. 1617, 1625. “[A] circuit split has arisen over whether ‘claims . . . pending,’ in this context, refers to underlying claims for payment from the government or the legal claims presented in the action itself.” U.S. ex. rel. Ahumada v. NISH, 756 F.3d 268, 280 n.7 (4th Cir. 2014). The Fourth Circuit has not taken a position on the proper interpretation, see id., but this Court need not resolve this issue in considering the present Motion to Dismiss, as the result is the same either way.

<sup>5</sup> In Counts 4 and 5, which are not asserted against Defendant Quintiles, Walterspiel alleges that false claims for payment were made by Defendant Bayer after the Cipro market exclusivity period expired (Count 4), and that Defendant Bayer presented false claims for payment to the United States during the exclusivity period and after it ended, under contracts related to the purchase of drugs and products other than Cipro (Count 5).

at 678. “In addition to meeting the plausibility standard of [Iqbal], fraud claims under the [False Claims] Act must be pleaded with particularity pursuant to Rule 9(b) of the Federal Rules of Civil Procedure.” Nathan, 707 F.3d at 455. To state with “particularity” the circumstances constituting fraud, “an FCA plaintiff must, at a minimum, describe ‘the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.’” United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008) (quoting Harrison, 176 F.3d at 784). To the extent that Defendant Quintiles contends that Walterspiel failed to describe the fraudulent acts with the particularity required by Federal Rule of Civil Procedure 9(b), this contention is treated as an argument under Rule 12(b)(6). Harrison, 176 F.3d at 783 n.5 (“[L]ack of compliance with Rule 9(b)’s pleading requirements is treated as a failure to state a claim under Rule 12(b)(6).”)

The essential elements that Walterspiel must plead with respect to his claims of violations of the FCA are: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that “involved a claim” made to the Government for payment. United States ex rel. Ahumada v. NISH, 756 F.3d 268, 280 (4th Cir. 2014); see also United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 700 & n.6 (4th Cir. 2014); Harrison, 176 F.3d at 788.

In this case, the Complaint’s allegations fail to plead the essential elements with the particularity required by Rule 9(b). The Complaint contains no allegation of any detail regarding the claims made on government funds in any respect. The Complaint refers vaguely to contracts for the purchase of Cipro, and includes a series of estimates regarding what portion of Cipro



sales are attributable to the Government.<sup>6</sup> However, Walterspiel’s generalized estimates are vague and do not identify any specific claim on the government for payment, and this alone warrants dismissal of Walterspiel’s claims against Defendant Quintiles. Cf. Nathan, 707 F.3d at 456 (holding that “the particularity requirement of Rule 9(b) does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government”(internal quotation omitted)).

Moreover, the Complaint’s allegations of the role Defendant Quintiles, or the roles of employees of Defendant Quintiles, are vague, ambiguous, and appear to be an impermissible “fishing expedition.” Walterspiel alleges that Jane and John Doe worked for Quintiles. According to the Complaint, Jane Doe “observed that the investigators had not followed the study protocol and its instructions (in a blatant manner by falsifying data) but knowingly did not report this finding to her superiors (*or did so and her superiors and/ or Bayer failed to inform the United States*).” (Compl. ¶ 26 (emphasis added).) Similarly, the Complaint alleges that John Doe “observed from irregularities in the data that investigators could not have obtained such data by following the study protocol, but knowingly did not report this finding to his superiors or Bayer notwithstanding his obligations to do so (*or did so and his superiors and/ or Bayer failed to inform the United States*).” (Id. ¶ 30 (emphasis added).) Such allegations suggest a lack of actual knowledge

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<sup>6</sup> In addition, although Walterspiel’s claims hinge on the government’s ability to contract for the purchase of generic drugs at a much reduced price, the Complaint omits any factual allegations regarding the availability of those generics had the FDA not granted Defendant Bayer the six-month market exclusivity extension.

regarding the events underlying Walterspiel's Complaint, and, in essence, allege nothing at all. Allowing Walterspiel to proceed to discovery on such allegations would defeat the purpose of Rule 9(b).

In addition, Walterspiel's allegations against Defendant Quintiles simply do not cross the line to plausible. Defendant Quintiles is one step removed from any alleged fraud on the Government. Defendant Quintiles did not present the data to the FDA, and the Complaint repeatedly alleges instances in which Defendant Bayer was purportedly informed of the alleged concerns with the data. Even more importantly, there are no allegations that Defendant Quintiles was involved in any way in any subsequent claims for payment, nor does it appear that any purported fraud by Defendant Quintiles was material to any such claims for payment. Cf. Nathan, 707 F.3d at 456 (“[L]iability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.”); Harrison, 176 F.3d at 788 (noting that a falsification on a form “not itself a claim for payment, not apparently required for payment, and not connected to substantive conditions required for payment, is not material”).<sup>7</sup>

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<sup>7</sup> The Court also notes that to the extent Walterspiel's claims are based on alleged failures to comply with FDA regulatory requirements, the Court of Appeals for the Fourth Circuit recently considered an FCA case involving alleged violation of FDA safety regulations and subsequent Medicare and Medicaid reimbursement claims, and concluded that “relator's allegations of regulatory violations fail to support FCA liability.” United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014). The Fourth Circuit noted that “[w]ere we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct. When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could ‘short-circuit the very remedial process the Government has established to address non-compliance with those regulations.’” See also United States ex rel. Ge v. Takeda Pharmaceutical Co. Ltd., 737 F.3d 116 (1st Cir. 2013).

In addition, the Court also notes that as a general matter, Walterspiel has shown only the most attenuated connection between the purported claims for payment for Cipro at non-generic prices and the allegedly false

Finally, with respect to Walterspiel's conspiracy claims, "Relator must allege with particularity facts (1) to support the formation of an unlawful agreement between the conspirators to get a false claim paid, and (2) at least one overt act in furtherance of the conspiracy." United States ex rel. Ahumada v. National Ctr. for Employment of the Disabled, No. 1:06-cv-713, 2013 WL 2322836, at \*4 (E.D. Va. May 22, 2013) (citing United States ex rel. Godfrey v. KBR, INC., 360 F. App'x 407, 413 (4th Cir. 2010) and Harrison, 176 F.3d at 790), aff'd, 756 F.3d 268 (4th Cir. 2014). "The conspirators must also have agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim." Id. (internal quotation omitted). No such factual allegations appear in the Complaint.

In sum, rather than plead his claims with the specificity required by Rule 9(b), Walterspiel appears to have pled alternative scenarios in the hopes that one of them may amount to a viable claim under the False Claims Act. In the end, the allegations fall far short of the requirements of Rule 9(b). Accordingly, Walterspiel's claims against Defendant Quintiles (Counts 1-3) should be dismissed.<sup>8</sup>

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information included in the apparently unrelated FDA submission. Walterspiel has cited no cases that would recognize an FCA action in those circumstances. However, the Court need not further consider the outer contours of a potential FCA claim here, given the multiple other failings noted above.

<sup>8</sup> While Walterspiel's insufficiently-detailed pleading forecloses his claims under either the pre- or post-2009 version of 31 U.S.C. § 3729, his claims would also fail under the pre-2009 version of 31 U.S.C. § 3729(a)(2), if it were deemed to apply, for the reasons stated in Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

B. Leave to File Amended Complaint

Walterspiel, in his Response Brief, requests leave to file an amended complaint should the Court find the instant allegations insufficient. He argues that more details on the particular government contracts for purchase of Cipro may be available “from materials posted on the internet which [Walterspiel] has obtained and to some extent could be obtained via the Freedom of Information Act.” (Pl.’s Response [Doc. #77] at 19.) As to additional details regarding the alleged falsification of data, Walterspiel says that “discovery may be required to obtain most of that type of evidence which remains under the control of the defendants.” (Id. at 20.)

However, Walterspiel has not filed an Amended Complaint, nor has he filed a motion for leave to amend his Complaint. To obtain leave of court, he must file a motion. See Fed. R. Civ. P. 7(b)(1) (a request for a court order must be made by motion). This Court’s local rules also require that any motion for leave to file an amended complaint include a copy of the proposed amended pleading. M.D.N.C. LR 15.1. Walterspiel has failed to follow these rules, and therefore his improperly-raised request for leave to amend should be denied.<sup>9</sup> Accordingly, Walterspiel’s “request” for leave to amend should be denied. See Rostholder, 745 F.3d at 703 (no abuse of discretion to deny request for leave to amend complaint where no proposed amended complaint was tendered in violation of the court’s local rule); Francis v. Giacomelli, 588 F.3d 186, 197 (4th Cir. 2009) (same).

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<sup>9</sup> Moreover, and in any event, his assertions regarding the details to be added appear purely speculative and insufficient to cure the failures noted above, and the lack of a proposed amended pleading precludes further analysis of this request.

The Court also notes that in the circumstances, there is no basis to allow discovery so that Walterspiel can attempt to obtain the facts necessary to state a valid claim. In Harrison, the Fourth Circuit stated that “[t]he clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through discovery after the complaint is filed.” Harrison, 176 F.3d at 789 (internal quotation omitted); see also Wilson, 525 F.3d at 380 (“Thus, if allowed to go forward, Relators’ FCA claim would have to rest primarily on facts learned through the costly process of discovery. This is precisely what Rule 9(b) seeks to prevent.”); Nathan, 707 F.3d at 456 (“Moreover, we have emphasized that a claim brought under the Act that rests primarily on facts learned through the costly process of discovery is precisely what Rule 9(b) seeks to prevent.” (internal quotation omitted)). Accordingly, Walterspiel’s request for leave to amend after discovery should be denied on this basis as well.

C. Service on Defendant Bayer

As a final matter, Defendant Bayer has yet to appear, and Walterspiel has been notified on several occasions of the need to adequately serve process on Defendant Bayer. Most recently, the Clerk of Court sent a Notice of Failure to Make Services within 120 Days [Doc. #81]. Walterspiel responded to that Notice by recounting his efforts to date to effectuate service of process on Defendant Bayer. (See Resp. [Doc. #82].) Specifically, Walterspiel argues that he has properly served Defendant Bayer in two ways: first, by causing the summons and complaint to be served on Bayer Corporation, a domestic subsidiary of Defendant Bayer, and, second, by sending the summons and complaint, via FedEx next day delivery, to Bayer A.G.’s headquarters in Germany pursuant to Article 10(a) of the Hague Convention.

Under Federal Rule of Civil Procedure 4(h), service on a corporation may be made outside the United States as provided in Rule 4(f), including by any internationally agreed means of service that is reasonably calculated to give notice, such as the methods authorized by the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents. However, Plaintiff's contention that he properly served Defendant Bayer under Article 10(a) of the Hague Convention falls short. Article 10(a) of the Hague Convention states: "*Provided the State of destination does not object*, the present Convention shall not interfere with – (a) the freedom to send judicial documents, by postal channels, directly to persons abroad . . . ." Hague Convention, 20 U.S.T 361, 363 (emphasis added).<sup>10</sup> However, "Germany . . . has expressly objected to service by mail, and requires that service be effected on the central authority." See Davies v. Jobs & Adverts Online, GmbH, 94 F. Supp. 2d 719, 722 n.6 (E.D. Va. 2000); see also Table Reflecting Applicability of Articles 8(2), 10(a)(b) and (c), 15(2) and 16(3) of the Hague Service Convention (available at <http://www.hcch.net/upload/applicability14e.pdf>) (reflecting German opposition to Article 10(a)); Germany - Central Authority & practical information (available at [http://www.hcch.net/index\\_en.php?act=authorities.details&aid=257](http://www.hcch.net/index_en.php?act=authorities.details&aid=257)) (same); 2003 Responses to 2003 Questionnaire - Germany at 11 (available at [http://www.hcch.net/upload/wop/lse\\_de\\_tot.pdf](http://www.hcch.net/upload/wop/lse_de_tot.pdf)) ("Germany . . . has objected to the use of postal channels under Article 10 a) of the Convention."). That is, "[i]n accordance with paragraph 2(a) of Article 21

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<sup>10</sup> A Circuit split has arisen over whether Article 10(a) permits service of judicial documents. Although the Fourth Circuit has not yet addressed the issue, at least one district court has recognized that "the majority of district courts in the Fourth Circuit have . . . [held] that service by registered mail is appropriate under Article 10(a) of the Convention." Synchrude Canada Ltd. v. Highland Consulting Grp., Inc., 916 F. Supp. 2d 620, 625-26 (D. Md. 2013). Regardless, because Germany has objected to Article 10(a), service by mail is not sufficient in any event.

of the Convention, the Government of the Federal Republic of Germany objects to the use of methods of transmission pursuant to Articles 8 and 10. . . . Service pursuant to Article 10 of the Convention shall not be effected.” See Declaration 4 of Germany made under the Service Convention (available at [http://www.hcch.net/index\\_en.php?act=status.comment&csid=402&disp=resdn](http://www.hcch.net/index_en.php?act=status.comment&csid=402&disp=resdn)). Accordingly, Walterspiel’s attempted method of service was ineffective, and it appears that Walterspiel has failed to undertake sufficient efforts to understand and comply with the Hague Convention in order to properly effect service of process on Defendant Bayer.<sup>11</sup>

As to Walterspiel’s attempted service on Defendant Bayer’s domestic subsidiary, under Rule 4(h) and 4(e), a foreign corporation may be served in the United States by service on an agent authorized by law to receive service of process, or by otherwise following state law for service. “Where service on a domestic agent [of a foreign entity] is valid and complete under both state law and the Due Process Clause . . . the [Hague] Convention has no further implications.” Volkswagenwerk Aktiengesellschaft v. Schlunk, 486 U.S. 694, 707 (1988). However, an attempt to serve process on a foreign corporation by serving its domestic subsidiary depends upon whether the domestic subsidiary is the foreign corporation’s agent for service of process. Id. In this case, Walterspiel has put forth no evidence, or even argument, tending to show that Bayer Corporation was actually appointed as agent for Bayer A.G. for service of process, or that Bayer Corporation is sufficiently intertwined with Bayer A.G. so as

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<sup>11</sup> “The federal rules give no specific time limit on service outside of the United States, see Fed. R. Civ. P. 4(m), but courts have leave to dismiss for failure to serve abroad when a plaintiff is dilatory.” Feliz v. MacNeill, 493 F. App’x 128, 131 (1st Cir. 2012); see also Nylok Corp. v. Fastener World, Inc., 396 F.3d 805, 807 (7th Cir. 2005) (“[T]he amount of time allowed for foreign service is not unlimited.”).

to warrant deeming it Defendant Bayer's agent for purposes of service of process. Cf. In re Baycol Prods. Litigation, No. MDL NO. 1431, 2003 WL 24229818, at \*4 (D. Minn. Dec. 12, 2003) ("Nor has Plaintiff put forth any evidence that Bayer Corporation is authorized to accept service on behalf of Bayer AG. Finally, Plaintiff has not met her burden of showing that service upon a subsidiary constitutes service upon the parent."); Spangler v. Demshock, No. 2:09CV18, 2009 WL 2431412, at \*3-4 (W.D.N.C. May 20, 2009) (noting that the plaintiff had failed to cite any North Carolina or federal law which holds that service of a subsidiary is service of a parent corporation, and plaintiff would have to show facts to establish that the subsidiary was the alter ego or instrumentality of the parent); Bays v. Mills Supplies, Inc., No. 1:10-CV-00432, 2011 WL 781464, at \*2 (N.D. Ind. Feb. 28, 2011) (noting that the plaintiff made no attempt to show that parent had requisite degree of control over subsidiary so as to consider subsidiary an agent for service of process); see also Foster v. Bridgestone Am., Inc., No. 11-0175-WS-N, 2011 WL 3606983 (S.D. Ala. Aug. 15, 2011); U.S. ex rel. Thomas v. Siemens AG, 708 F. Supp. 2d 505 (E.D. Pa. 2010); University of Pittsburgh v. Hedrick, No. 06-MC-176, 2006 WL 3370365, at \*1 (E.D.N.Y. Nov. 20, 2006).

Given the numerous notifications to Walterspiel regarding the lack of proper service on Defendant Bayer, Walterspiel's apparent minimal efforts to comply with the Hague Convention or otherwise demonstrate the propriety of his attempted methods of service, and the extended period of time Walterspiel has now had to rectify these issues, no cause exists to further extend the time for effecting service of process on Defendant Bayer, and the Court should dismiss the claims against Defendant Bayer without prejudice for failure to timely effect service of process.



Similarly as to the remaining Doe Defendants, because Walterspiel has failed to serve these Doe Defendants, the claims against the Doe Defendants should likewise be dismissed without prejudice.

### III. CONCLUSION

IT IS THEREFORE RECOMMENDED that the Motion to Dismiss filed by Defendant Quintiles [Doc. #72] be granted, and that all claims against Defendant Quintiles (Counts 1-3) be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6).

IT IS FURTHER RECOMMENDED that all claims against Defendant Bayer and the Doe Defendants be dismissed without prejudice for failure to timely serve process, and that this action be dismissed.

This, the 19th day of December, 2014.

/s/ Joi Elizabeth Peake  
United States Magistrate Judge